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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/04, 2/06, 6/18

A1

(11) International Publication Number: **WO 99/58083**

(43) International Publication Date: 18 November 1999 (18.11.99)

(21) International Application Number: PCT/CA99/00405

(22) International Filing Date: 7 May 1999 (07.05.99)

(30) Priority Data:

09/074,991	8 May 1998 (08.05.98)	US
09/087,375	29 May 1998 (29.05.98)	US

(81) Designated States: CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

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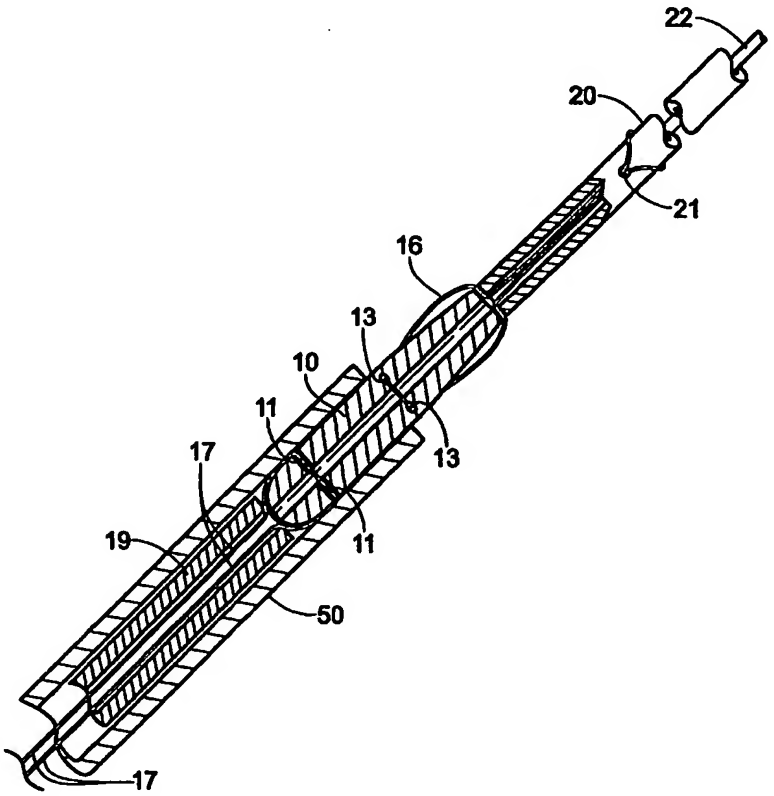
(54) Title: STENT PLACEMENT AND RETRIEVAL

(57) Abstract

Placement and non-surgical retrieval of a ureteral stent is accomplished in one embodiment by suspending a ferromagnetic bead from an indwelling stent. The bead is suspended by a flaccid tether that reduces the likelihood of patient irritation when a shortened stent is used. The bead, tether, and stent assembly are advanced into the patient as a unit via a conventional cystoscope. A magnet-tipped catheter is employed to engage the bead in the bladder and permit removal of the connected stent as the catheter is withdrawn. In another embodiment, a collapsible basket is suspended from an indwelling stent. The basket is suspended by a flaccid tether that reduces the likelihood of patient irritation when a shortened stent is used. The basket is deployed in the bladder into its normal, generally ovoid configuration. A retrieval instrument having extensible graspers readily engage the hoop or ribs that make up the basket, thereby permitting retrieval of the connected stent as the instrument is withdrawn.



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STENT PLACEMENT AND RETRIEVAL

Technical Field

This invention relates to placement and retrieval of full-length or shortened ureteral stents, or stents in other hollow or tubular structures, which stents may be removed without the use of surgical, endoscopic, or fluoroscopic devices.

Background of the Invention

Ureteral stents are used to provide drainage of urine from the kidneys to the bladder. The stent is a flexible, tubular structure that is constructed of relatively inert material. The stent is perforated to have a plurality of small drainage holes along its length. Some stents are shaped to define "hooks" at either end. The hooks prevent migration of the tube from the kidney toward the bladder or from the bladder upwards.

Normally, indwelling stents must be periodically removed or replaced. Conventional stent retrieval procedures are complex and may be painful, sometimes requiring general anesthesia.

The presence of a stent within the lower ureter and within the bladder may cause considerable irritation to some patients. To alleviate this irritation, stents can be shortened. The stent is shortened at the distal (bladder) end. Thus, the distal end of the shortened stent may reside in the ureter, remote from the bladder and the ureteral orifice. The ureteral orifice is the junction of the ureter and the bladder. A thin thread may be attached to the shortened stent to extend into the bladder and provide a means for later removing the stent. To remove the shortened stent, the thread must be endoscopically visualized, grasped, and withdrawn. Although this is a relatively simple procedure, it requires specialized instruments used by an urologist in a sterile setting. Here, too, general anesthesia is sometimes required.

Summary of the Inventi n

The present system provides a stent assembly, system, and method for placement of ureteral stents, and for non-surgical retrieval of the stent assembly.

As one aspect of the invention, a conventional stent is modified to have connected to it a ferromagnetic member. The ferromagnetic member is biocompatible and is in the form of an elongated bead and is connected to the distal end of the stent by a tether. This permits the ferromagnetic member to be disposed in the bladder, suspended from the stent while the stent is positioned in the ureter. The bead is inserted at the time of insertion of the stent via a standard cystoscope that includes a guide wire and pusher.

The stent may be shortened to a length of choice prior to insertion, or left full-length. The shortened stent and tethered bead are inserted as a unit. The bead is shaped to temporarily penetrate the ureter as the bead is pushed with the shortened stent into the ureter to the desired position of the stent. The bead is provided with a mechanism that permits only the bead to be withdrawn from the ureter, pulled back into the bladder under visual control, once the shortened stent is properly positioned.

If a full-length stent is used, the bead does not, even temporarily, penetrate the ureter.

The stent assembly is readily removed by a non-surgical procedure that involves blind insertion of a magnet-tipped catheter into the bladder. The magnet engages the ferromagnetic bead, and the overall stent/tether/bead assembly is easily removed as the catheter is withdrawn.

As another aspect of the invention, a conventional stent is modified to have connected to it a collapsible basket. The basket is biocompatible and is in the form of a spherical or ovoid member that is connected to the distal end of the stent by a tether. This permits the basket to be disposed in the bladder, suspended from the stent while the stent is positioned in the ureter or in the

bladder. The basket is inserted at the time of insertion of the stent via a standard cystoscope that includes a guide wire and pusher.

As above, the stent may be shortened to a length of choice prior to insertion, or left full-length. The shortened stent and tethered basket are moved into the bladder as a unit. The basket is collapsible, but permitted to assume its normal spherical/ovoid shape in the bladder as the shortened stent is moved into the ureter to the desired position of the stent. The basket resumes its spherical shape when all constraining forces, such as the urethra, are remove from it. When a shortened stent is used, the tether length is long enough to ensure that the basket does not enter the ureter, and is located away from the ureter inside of the bladder.

This stent assembly is readily removed by a non-surgical procedure that involves blind insertion of a retrieval instrument into the bladder. The instrument is flexible and tubular and includes a plurality of grasping members that extend from the interior of the instrument. The instrument can be either advanced by itself in the retracted state into the bladder, or through a catheter. When in the bladder, the grasping members are extended. The extended grasping members readily engage the basket in the bladder. The grasping members are then retracted into the tubular instrument, thereby securing together the instrument and basket. The instrument can be withdrawn into the interior of the catheter or directly from the urethra. Thus, the overall stent/tether/basket assembly is easily removed as the tubular instrument and catheter are withdrawn.

As another aspect of the invention, the basket is configured as a generally circular hoop. A number of elongated, flexible ribs are joined at opposing ends, and the ribs are attached to the hoop at the mid-portions of the ribs. The ribs may be either flattened or cylindrical in cross section. The rib and hoop members are collapsible by applying a relatively light force, but normally assume a deployed, spherical or ovoid configuration that is easily engaged by the grasping members of the retrieval instrument.

As another aspect of this invention, the tether is flaccid, thereby permitting either the bead or suspended basket to move relative to the indwelling stent. This arrangement minimizes patient irritation that might otherwise occur if the tether were somewhat rigid or resilient.

Description of the Drawings

Fig. 1 is a sectional view of the bead component of a preferred embodiment of the stent placement and retrieval system of the present invention.

Fig. 2 is a pictorial view of the bead with a tether provided on the proximal end of the bead.

Fig. 3 is an enlarged side view of a needle that is useful for connecting the tether to a conventional ureteral stent.

Fig. 4 is a view, partly in section, of a magnet-tipped catheter component of the system.

Fig. 5 shows the primary components of one embodiment of the system, which can be advanced, as a unit, into position within the patient via a conventional cystoscope, guide wire, and pusher.

Fig. 6 illustrates the advancement of a full-length stent, tether, and bead assembly, relative to the ureteral orifice, as the stent is moved onto position.

Fig. 7 illustrates a full-length stent positioned in the ureter with the insertion instruments removed and the tethered bead suspended in the bladder.

Fig. 8 illustrates the advancement of a shortened stent, tether, and bead assembly, relative to the ureteral orifice, as the stent is moved onto position.

Fig. 9 illustrates the step of withdrawing the bead from the ureter once the shortened stent is pushed into proper position.

Fig. 10 illustrates a shortened stent positioned in the ureter with the insertion instruments removed and the tethered bead suspended in the bladder.

Fig. 11 is an enlarged view of the basket component and tether of another preferred embodiment of the stent placement and retrieval system of the present invention.

Fig. 12 is a view, partly in section, showing the primary components of the system, which can be advanced, as a unit, into position within the patient via a conventional cystoscope, guide wire, and pusher.

Fig. 13 illustrates the advancement of a full-length stent, tether, and basket assembly, relative to the ureteral orifice, as the stent is moved onto position.

Fig. 14 illustrates a full-length stent positioned in the ureter with the insertion instruments removed and the tethered basket suspended in the bladder.

Fig. 15 illustrates the advancement of a shortened stent, tether, and basket assembly, relative to the ureteral orifice, as the stent is moved onto position.

Fig. 16 illustrates a shortened stent positioned in the ureter with the insertion instruments removed and the tethered basket suspended in the bladder.

Fig. 17 shows a retrieval instrument used for non-visual, non-surgical retrieval of the stent and basket.

Description of Preferred Embodiments

The preferred embodiment of the bead component 10 of the present invention is shown enlarged in Fig. 1. Fig. 2 depicts the bead 10 and connected tether 16. As will be explained, the tethered bead is connected to the distal end of a conventional stent (full-length, or shortened) for the purpose of converting that stent into one that may be non-surgically removed using a magnet-tipped catheter.

The bead 10 is, primarily, a ferromagnetic member. In this regard, the term "ferromagnetic" is meant to include the characteristic of substances comprised of iron, nickel, or cobalt and various alloys that are attracted to a magnet. Preferably, the bead 10 is stainless steel and may be coated with a smooth layer of, for example, polytetrafluoroethylene, which can be characterized as "biocompatible" in that it prevents reaction of the bead 10 with urine. It is contemplated that the bead 10 may be a magnet.

In the present embodiment, the bead is an elongated member, between 6 mm and 12 mm in length. The preferred shape of the bead 10 features a large-radius, proximal end taper 14. That is, about one-third of the length of the bead tapers from the full outside diameter of the bead (between 2.25 and 4.5 mm) to a minimum outside diameter of about 1.8 mm at the proximal end 32 of the bead. The outside diameter of the proximal end 32 of the bead generally matches that of the distal end of the stent 20 (Fig. 5).

The distal end 34 of the bead 10 has a smaller-radius taper 15. As will become clear, the tapered shape of both ends of the bead facilitates movement of the bead through a cystoscope, and, in the case of a shortened stent, into and out of the ureter.

As best shown in Figs. 1 and 5, the bead 10 includes a central (i.e., through its long axis) guide lumen 12. The guide lumen 12 allows a commonly used guide wire 22 to be passed through the bead, thereby enabling the bead to be later advanced up the guide wire 22 as the stent and

bead 10 are positioned within the patient, typically under fluoroscopic control.

As noted, the bead 10 is connected to the stent 20 by the tether 16. To this end, the bead 10 has, located near its midpoint, a pair of small-diameter openings 13. The openings 13 are spaced apart and extend through the bead in a direction generally perpendicular to the long axis of the bead. Alternatively the openings may be angulated and diverging in the direction toward the proximal end 32 of the bead. The tether 16 is threaded through both openings 13 to connect the tether to the bead 10. Alternatively, each free end of the tether is fixed, such as by crimping, to one of the openings. The portion of the tether that extends from the bead defines an endless loop that is connectable to the conventional, perforated stent, as described below.

It is contemplated that a single transverse opening 13 in the bead would suffice for connecting the tether and bead. The tether would be passed through the single opening before being formed into the endless loop.

Referring, momentarily, to Fig. 7, that figure shows a full-length stent 20 positioned within a ureter 52. The distal end 40 of the stent has attached to it a tether 16 that connects the stent to the bead 10 which is disposed in the bladder 38. In this embodiment, the stent 20 extends through the ureteral orifice 44.

The tether 16 is made of nylon or other biocompatible, thin, flexible, high-break-force line. The tether is flaccid in the sense that it lacks any significant resilience, and it readily yields to all but tensile force. As a result, the bead --once disposed in the bladder 38-- is suspended from the distal end 40 of a stent and is not forced or urged against the wall of the bladder 38. This suspension of the bead, therefore, minimizes irritation of the bladder, which might otherwise be present if the bead were in some way urged into contact with the wall of the bladder.

Even though Fig. 7 illustrates an indwelling stent 20 having a hook-shaped distal end 40 (The hook is intended to halt migration of the stent

toward the kidney.), it is contemplated that no such hooked end is required. For instance, the stent 20 could be terminated with a straight nd, such that the portion of the stent illustrated below the dashed line 46 in Fig. 7 would not be present. The bead 10, therefore, would be suspended by the tether from near that location 46 of the distal end of the stent. In this arrangement, the possibility of irritation attributable to a relatively large, hooked end of the stent would be eliminated.

The bead 10 is generally free to rotate relative to the tether 16 to which it is connected. The tether is attached to the bead at a location generally aligned with the center of mass of the bead, but offset somewhat from the long axis of the bead. As a result, the bead tends to hang from the tether with its long axis oriented generally perpendicular to the length of the ureter, as shown in Figs. 7 and 10, thereby preventing the suspended bead from migrating into the ureteral orifice. Also, and irrespective of the orientation of the bead, the suspended bead 10 is sized so that it will not migrate into the ureter in the absence of a pushing force with the bead properly aligned with the ureter. Moreover, if the tether is made short enough, the bead thus prevents upward (toward the kidney) migration of the stent.

In instances where a shortened stent 23 is employed (that is, a stent having a distal end 42 that resides in the ureter 52, away from the ureteral orifice 44 -see Fig. 10), the thin, flaccid tether 16 extends between the distal end 42 of the shortened stent 23, through the ureteral orifice 44, to the bead 10 that is within the bladder 38. Thus, the very thin, flaccid tether prevents irritation that would occur as a result of the presence of an indwelling stent passing through the ureteral orifice.

Returning to Figs. 1, 2, and 5, the bead 10 is also provided with a larger diameter passage 11 that allows a flexible line 17 to be threaded through the bead. Such a line 17 would be employed for withdrawing the bead from the ureter to locate the bead in the bladder after a shortened stent is in position. This is explained more below.

As noted above, the system of the present invention may be used with any conventional ureteral stent, such as those designated "*Bander Ureteral Diversion Stents*" and manufactured by Cook Urological Incorporated, of Spencer, Indiana. Such stents are flexible, tubular members that, in addition to a central lumen, include spaced-apart perforations 21 (Fig. 5) that serve as drain holes. Described next is an elegantly simple technique for attaching the looped tether to a selected portion on the distal end of the stent.

Fig. 3 shows an elongated instrument or needle 31 for attaching the tether 16 and stent 20. The needle 31 is pointed but not sharp at its proximal end 27. The needle 31 also has a slot 28 near its proximal end, thus defining a hook at that end of the needle. The distal end of the needle is fastened to a handle 29.

The needle is sized to pass its hooked end through a perforation 21 from outside the stent to inside of the central lumen of the stent, without damaging the stent. The end 27 of the needle is then protruded from the distal end of the stent. The tether 16 is moved into the slot 28, and the needle, while engaging the tether is retracted through the lumen and perforation so that a portion of the tether loop is exposed outside of the stent, emerging from the perforation. The proximal end of the stent is moved through this loop portion, which will now provide an assured connection of the bead 10 and tether 16 to a stent, as best seen in Fig. 5.

Fig. 5 shows an assemblage including a guide wire 22, a hollow pusher 19, the bead 10, and the stent 20 all being advanced as a unit through and from a cystoscope 50. Fig. 5 also shows a positioning line 17 threaded through the passage 11 in the bead 10 and then through the inner lumen of the pusher 19. This positioning line 17 extends from the bead to the outside of the cystoscope, exposed for grasping by the user. The bead 10 is fastened to the stent 20 by the tether 16, which, as described above, has been threaded through the central lumen of the stent 20 and through the perforation 21 of the stent 20 then looped around the stent 20 at the level of the selected

perforation 21 of the stent 20.

Fig. 6 shows the initial stage of inserting a full-length stent 20 which has a bead 10 connected to its distal end. This stage positions the distal end of the stent 20 in the bladder 38 with the bead 10 well away from the ureteral orifice 44. Once the distal end of the stent 20 is in the bladder and the proximal end of the stent is in the kidney (not shown), the guide wire 22 and pusher 19 are removed. This allows the stent 20 to assume its hooked-end position, said to help prevent migration of the stent into the ureter (Fig. 7). As noted, in this position, the bead 10 is suspended from the stent 20 by the tether 16.

Although Fig. 5 shows the assembly with positioning line 17 in place, it will be appreciated that for the placement of full-length stents (Figs. 6 and 7) there is no need for the line, and it may be omitted.

Figs. 8, 9, and 10 show three stages of the insertion of a shortened stent 23. The distal end 42 of such a stent is ultimately positioned in the ureter 52. To accomplish this positioning, the bead 10 and the proximal end of the pusher 19 are pushed into the ureter 52 as shown in Fig. 8. That is, the bead 10 completely or partially penetrates (proximal-end first) the ureter 52. The guide wire 22 is then withdrawn.

The second stage of the positioning of the shortened-stent system, shown in Fig. 9, comprises the removal of the pusher 19, followed by the bead 10. Preferably, the bead is removed by pulling on the positioning line 17 (that is, the outer ends of the line that are exposed to the user) after, or simultaneously with removing the pusher 19. This withdraws the bead from the ureter, distal-end first. In this regard, the tether 16 is of a length such that there is sufficient slack to allow the withdrawal of the bead from the ureter to the bladder without pulling the stent 23 toward the bladder. Once the bead is withdrawn, the line 17 is removed from (slid through) the bead, leaving the bead 10 suspended by the tether 16 spaced from the ureteral orifice 44 and disposed within the bladder 38.

Preferably, the passage 11 through which the positioning line 17 passes is located near the distal end and passes diametrically through (or close to diametrically through) that end of the bead. This arrangement is best to ensure that the bead is withdrawn from the ureter along a straight path to avoid damage to the wall of the ureter.

Fig. 4 depicts a component of the system that enables non-surgical removal (that is, no endoscopy is required) of both a full-length and shortened stent. The component, designated a retrieval catheter 24 comprises a conventional Foley catheter that is modified to serve as the retrieval catheter 24. Specifically, the catheter includes a magnet 26 mounted at its proximal tip. The magnet 26 is part of an assembly that consists of a grooved end 25 that is inserted into the catheter and acts as a barb to retain the magnet affixed to the catheter 24. The magnetic material of the retrieval magnet 26 may be covered with a biocompatible inert layer 30.

The magnet-tipped end of the retrieval catheter is inserted, through the urethra and into the bladder, whence it magnetically engages the suspended ferromagnetic bead 10. Then, the withdrawal of the catheter 24 brings with it the bead and tether-connected stent. Preferably, the magnet 26 is rounded to avoid injury to the patient.

As the magnet 26 approaches the bead 10, the magnetic flux acting on the bead 10 should cause the bead to rotate relative to the tether from its normal, suspended position, so that one of the ends of the bead swings about 90 degrees into contact with the magnet 26. As a result, the bead will be oriented generally coaxially with the end of the retrieval catheter 24 that carries the magnet 26. If this orientation is not attained in the bladder, as the retrieval catheter magnet and bead enter the urethra passage, the urethra will assure the axial alignment of the assembly. This orientation is desired for sure and comfortable removal of the bead through the urethra.

The indwelling bead could be made as a magnet, with the retrieval catheter tipped with ferromagnetic material. Although a rare-earth magnet is

preferred, other types, including electromagnets It will be appreciated that this rotation of the b ad will be assured where the bead is magnetized, and one of its ends has a polarity opposite that of the catheter magnet 26, could be employed with the retrieval catheter. In addition, the bead may be of a more ball shape rather than the described elongated bead.

Another embodiment of the present invention includes a basket component 110, shown enlarged in Fig. 11, along with the connected tether 116. As will be explained, the tethered basket is connected to the distal end of a conventional stent (full-length, or shortened) for the purpose of converting that stent into one that may be non-surgically removed using an instrument that readily grasps the basket.

The basket 110 comprises interconnected, spaced apart members that provides several segments to which one or more hook-shaped grasping members can be engaged, as described below. The basket may be formed of nylon or polypropylene, or any other suitable resilient material with either a flattened or round cross section. Preferably, the material is "biocompatible" in that it prevents reaction of the basket 110 with urine. It is contemplated that the basket 110 may be metal or metal alloy, such as stainless steel or nitinol.

In a preferred embodiment, the members that make up the basket 110 include a number of elongated ribs 112. The ribs are joined together (such as by bonding, heat welding etc) at the distal end 114 of the basket. The opposite ends of the ribs 112 are similarly joined at the proximal end 113 of the basket. A generally circular hoop 122 is attached close to the mid-portion of each rib 112. The ribs are preferably evenly spaced apart about the circumference of the hoop. Three or more ribs are preferred.

As noted, the hoop 122 and ribs 112 are formed of resilient material that normally assumes a deployed configuration as shown in Figs. 11, 14, and 16. That is, the components of the basket, with no forces acting upon them, assume a curved configuration. The material remains flexible, however, so that the basket may b readily collapsed for delivery into the patient's bladder,

as described below.

In the pr sent embodiment, the basket is an elongated member, between about 10 mm and 20 mm in diameter as deployed. The preferred shape of the basket 110 is spherical or ovoid.

It is contemplated that one or all of the ribs 112 may be made of merely flexible material (that is, not necessarily resilient) that is attached to a resilient, circular hoop 122. In such an arrangement, the overall basket 110 will still assume a generally spherical shape as shown. Similarly, the hoop 122 need not be made of resilient material, as long as there is sufficient resilience in the ribs 112 to move the basket into the spherical, deployed configuration.

As best shown in Fig. 12, the basket 110 collapses to fit inside of a tubular cystoscope 140, within the annular space defined between a pusher 120 and the cystoscope 140. This compact, collapsed configuration enables the basket to be later advanced through the urethra and into the bladder 141 as later described.

As noted, the basket 110 is connected to a stent 130 by the tether 116. To this end, the basket 110 has fastened to its proximal end 113 the ends of the tether 116. Thus, the portion of the tether that extends from the basket 110 defines an endless loop that is connectable to the conventional, perforated stent, as described below.

It is contemplated that two of the ribs 112 may be extensions of the tether 116, as long as the remaining ribs and/or hoop provide sufficient resilience to form the generally spherical basket.

The tether 116 is made of a nylon or other biocompatible, thin, flexible, high-break-force line. The tether is flaccid in the sense that it lacks any significant resilience, and it readily yields to all but tensile force. As a result, the basket --once disposed in the bladder 141-- is suspended from the distal end 132 of a stent and is not forced or urged against the wall of the bladder

(s e, for example, Fig. 14). This suspension of the basket, therefore, minimizes irritation of the bladder, which might otherwise be present if the basket were in some way urged into contact with the wall of the bladder.

Even though Fig. 14 illustrates an indwelling stent 130 having a hook-shaped distal end 132 (The hook is intended to halt migration of the stent toward the kidney.), it is contemplated that no such hooked end is required. For instance, the stent 130 could be terminated with a straight end. The basket 110, therefore, would be suspended by the tether from near the distal end of the straight stent. In this arrangement, the possibility of irritation attributable to a relatively large, hooked end of the stent would be eliminated.

The basket 110 is generally free to move relative to the tether 116 to which it is connected. In the bladder 141 the basket is free to assume its deployed configuration, the size of which is considerably greater than that of the ureter. Thus the deployed basket is unable to migrate into the ureter. Moreover, if the tether is made short enough, the basket thus prevents upward (toward the kidney) migration of the stent 130.

In instances where a shortened stent 133 is employed (that is, a stent having a distal end 132 that resides in the ureter 145, away from the ureteral orifice 144 -see Fig. 16), the thin, flaccid tether 116 extends between the distal end 132 of the shortened stent 133, through the ureteral orifice 144, to the basket 110 that is within the bladder 141. Thus, the very thin, flaccid tether prevents irritation that would occur as a result of the presence of an indwelling stent passing through the ureteral orifice.

As noted above, the system of the present invention may be used with any conventional ureteral stent, such as those designated "*Bander Ureteral Diversion Stents*" and manufactured by Cook Urological Incorporated, of Spencer, Indiana. Such stents are flexible, tubular members that, in addition to a central lumen, include spaced-apart perforations 131 (Fig. 12) that serve as drain holes. Described next is an elegantly simple technique for attaching the looped tether to a selected portion on the distal nd of the stent.

Fig. 2 shows an elongated instrument or blunt needle 31 for attaching the tether 116 and stent 130. The needle 31 is blunt at its proximal end 27. The needle 31 also has a slot 28 near its proximal end, thus defining a hook at that end of the needle. The distal end of the needle is fastened to a handle 29.

The needle is sized to pass its hooked end through a perforation 131 from outside the stent to inside of the central lumen of the stent, without damaging the stent. The end 27 of the needle is then protruded from the distal end of the stent. The tether 116 is moved into the slot 28, and the needle, while engaging the tether, is retracted through the lumen and perforation so that a portion of the tether loop is exposed outside of the stent, emerging from the perforation. The proximal end of the stent is moved through this loop portion, which will now provide an assured connection of the basket 110 and tether 116 to a stent, as best seen in Fig. 12.

Fig. 12 shows an assemblage including a guide wire 121, a hollow pusher 120, the basket 110, and the stent 130 all being advanced as a unit through and from the cystoscope 140. The basket 110 is collapsed within the annular space defined between a pusher 120 and the cystoscope 140. Moreover, the basket 110 is fastened to the stent 130 by the tether 116, which, as described above, has been threaded through the central lumen of the stent 130 and through the perforation 131 of the stent 130 then looped around the stent 130 at the level of the selected perforation 131 of the stent 130.

Fig. 13 shows the initial stage of inserting a full-length stent 130, which has the basket 110 connected via the tether 116 to its distal end. This stage positions the distal end 132 of the stent 130 in the bladder 141 with the basket 110 away from the ureteral orifice 144. Once the distal end of the stent 130 is in the bladder and the proximal end of the stent is in the kidney (not shown), the guide wire 121 and pusher 120 and cystoscope 140 (not shown in Fig. 13) are removed. This allows the stent 130 to assume its hooked-end position,

said to help prevent migration of the stent into the ureter (Fig. 14). Also, the basket 110 is free to resil into its deployed position and spherical or ovoid shape, suspended from the stent 130 by the tether 116.

Figs. 15 and 16 show two stages of the insertion of a shortened stent 133. The distal end 132 of such a stent is ultimately positioned in the ureter 145. To accomplish this positioning, the proximal end of the pusher 120 is pushed into the ureter 145 as shown in Fig. 15. In this embodiment, the length of the tether 116 is selected to be a length such that the basket 110 does not penetrate the ureter 145. Rather, the basket 110 remains in the bladder 141 as the stent 133 is finally positioned. Once the stent is in place, the guide wire 121, pusher 120 and cystoscope are withdrawn, and the basket assumes its full, deployed configuration (Fig. 16).

Fig. 17 depicts a component of the system that enables non-surgical retrieval (that is, no endoscopy is required) of both a full-length and shortened stent. The component, designated a retrieval instrument 150 comprises a flexible tube 155 that can be advanced up the urethra or through a conventionally positioned Foley catheter. A number of graspers 152 are slidable within the tube 155. As the tube 155 is advanced through the urethra to the bladder, the graspers 152 are fully retracted into the tube 155.

Once the end 154 of the tube 155 reaches the bladder, the graspers 152 are extended from the tube as shown in Fig. 17. The graspers are generally hook shaped and curved (at 151) to protrude radially outwardly. Each grasper is a rounded, bendable member having a blunted proximal end 153 to prevent bladder trauma. The instrument 150 with graspers extended is moved (rotated or reciprocated) to ensure that the exposed graspers engage the deployed basket. In this regard, the size and number of the graspers are such that very little manipulation of the instrument is needed to ensure engagement of the graspers and basket 110. Put another way, engagement of the graspers and basket is difficult to avoid when both are properly located in the bladder.

The graspers 152, with basket 110 engaged, are then retracted to secure the basket within the instrument 150. That instrument is then withdrawn into the catheter (or directly from the patient if a catheter is not employed). Then, the withdrawal of the catheter brings with it the basket 110 and tether-connected stent 132.

While the present invention has been described in terms of a preferred embodiment, it will be appreciated by one of ordinary skill that the spirit and scope of the invention is not limited to those embodiments. For example, the stent system may be universal in the sense that it may be employed in other cavities, etc. of the human anatomy. Thus the invention is considered to extend to the various modifications and equivalents as defined in the appended claims.

Claims

1. A stent assembly, comprising:
   a stent having a distal end;
   a ferromagnetic member; and
   a tether connecting the ferromagnetic member to the distal end of the stent.

2. The assembly of claim 1 wherein the tether is flaccid, thereby to enable the ferromagnetic member to be suspended and movable relative to the distal end of the stent.

3. The assembly of claim 1 wherein the tether is configured as an endless loop.

4. The assembly of claim 1 wherein the stent includes a central lumen and at least one perforation, the tether extending through the perforation and a portion of the lumen.

5. The assembly of claim 1 wherein the ferromagnetic member has an opening, into which opening the tether extends to secure the ferromagnetic member to the tether.

6. The assembly of claim 5 wherein the ferromagnetic member is an elongated member and wherein the opening extends in a direction that is generally perpendicular to a long axis of the member, the ferromagnetic member being rotatable relative to a portion of the tether that extends through the opening.

7. The assembly of claim 1 wherein the ferromagnetic member has opposing ends that are tapered to facilitate penetration into and withdrawal from a ureter into which the stent may be placed.

8. The assembly of claim 1 wherein the ferromagnetic member includes a transverse passage extending therethrough.

9. The assembly of claim 8 wherein the ferromagnetic member has a generally circular cross section and wherein the transverse passage extends diametrically through the ferromagnetic member.

10. The assembly of claim 1 wherein the ferromagnetic member is an elongated member and includes a lumen extending axially therethrough.

11. The assembly of claim 1 further comprising a catheter having magnet means mounted thereto for magnetically attracting the ferromagnetic member when the magnet means is brought into proximity with the ferromagnetic member.

12. An assembly for facilitating placement and removal of a stent, comprising:
a ferromagnetic member; and
a tether connected thereto, the tether extending from the ferromagnetic member thereby to enable the ferromagnetic member to be attached to a stent by the tether while the ferromagnetic member is remote from the stent.

13. The assembly of claim 12 wherein the tether is flaccid, thereby enabling the ferromagnetic member to be suspended from the tether and move freely relative to any stent to which the tether may be attached.

14. The assembly of claim 12 wherein the ferromagnetic member has an opening therein, into which opening the tether extends to connect the ferromagnetic member to the tether.

15. The assembly of claim 14 wherein the ferromagnetic member is an elongated member and wherein the opening extends in a direction that is generally perpendicular to a long axis of the member, the ferromagnetic member being rotatable relative to a portion of the tether that extends through the opening.

16. The assembly of claim 12 wherein the ferromagnetic member has

opposing ends that are tapered to facilitate penetration into and withdrawal from a ureter.

17. The assembly of claim 12 wherein the ferromagnetic member includes a transverse passage extending therethrough.

18. The assembly of claim 17 wherein the ferromagnetic member has a generally circular cross section and wherein the transverse passage extends diametrically through the ferromagnetic member.

19. The assembly of claim 12 wherein the ferromagnetic member is an elongated member and includes a lumen extending axially therethrough.

20. The assembly of claim 13 wherein the ferromagnetic member is an elongated member having a long axis and wherein the tether is connected at a location on the ferromagnetic member such that the ferromagnetic member is suspended by the tether with the long axis of the ferromagnetic member generally perpendicular to the length of the tether.

21. A method of converting a perforated ureteral stent into one that may be removed from a patient's ureter by use of a magnet, the method comprising the step of attaching to one end of the stent an elongated tether to which tether is connected a ferromagnetic member, thereby enabling the ferromagnetic member to be disposed within the patient's bladder and accessible to a magnet while the stent is in the ureter.

22. The method of claim 21 further including the step of sizing the stent so that the end of the stent to which the tether is attached is remote from the bladder while the stent is in the ureter and while the ferromagnetic member is disposed within the bladder.

23. A kit for converting a ureteral stent into one that may be removed from a patient's ureter by use of a magnet, wherein the stent has a central

lumen and at least one perforation, the kit comprising:

a ferromagnetic member; and

a tether connected to the ferromagnetic member, th tether including a loop that extends from the ferromagnetic member, thereby to enable the ferromagnetic member to be attached to a stent by the tether while the ferromagnetic member is remote from the stent; and

an elongated instrument sized to extend through both the lumen and perforation of the stent and engage the tether for connecting the tether to the stent.

24. The kit of claim 23 further comprising a passage formed through the ferromagnetic member at one end thereof to facilitate attachment of a line to the ferromagnetic member.

25. A method of inserting a ureteral stent, comprising the steps of:

locating the stent within a patient's ureter; and

suspending from the stent a ferromagnetic member to be disposed in the bladder of the patient.

26. The method of step 25 wherein the suspending step includes the step of temporarily penetrating the ureter with the ferromagnetic member.

27. The method of claim 26 wherein the locating step includes the step of guiding through a cystoscope a unit that includes the ferromagnetic member, stent, a guide wire, and a pusher member.

28. A stent assembly, comprising:

a stent having a distal end;

a collapsible basket; and

a tether connecting the basket to the distal end of the stent.

29. The assembly of claim 28 wherein the tether is flaccid, thereby to enable the basket to be suspended and movable relative to the distal end of the stent.

30. The assembly of claim 28 wherein the tether is configured as an endless loop.

31. The assembly of claim 28 wherein the stent includes a central lumen and at least one perforation, the tether extending through the perforation and a portion of the lumen.

32. The assembly of claim 28 wherein the basket comprises a hoop to which are attached a plurality of flexible ribs, the tether being secured to the basket.

33. The assembly of claim 32 wherein the basket ribs are generally elongated members having opposite ends that are joined together and mid-portions that are attached to the hoop, the basket normally assuming a generally ovoid shape.

34. The assembly of claim 32 wherein the basket has at least three ribs.

35. The assembly of claim 32 wherein the basket ribs are formed of resilient material and normally assume a curved configuration.

36. The assembly of claim 32 wherein the basket hoop is formed of resilient material and normally assumes a curved configuration.

37. The assembly of claim 28 wherein the assembly can be moved into a patient by a pusher member that is inside of a tubular member with an annular space present between the pusher member and the tubular member, the basket being collapsible into a configuration that fits into the annular space.

38. The assembly of claim 28 further comprising a retrieval instrument having grasping members for hooking the basket.

39. An assembly for facilitating placement and retrieval of a stent, comprising:
a collapsible basket; and
a tether connected thereto, the tether extending from the basket

thereby to enable the basket to be attached to a stent by the tether while the basket is remote from the stent.

40. The assembly of claim 39 wherein the tether is flaccid, thereby enabling the basket to be suspended from the tether and move freely relative to any stent to which the tether may be attached.

41. The assembly of claim 39 wherein the basket comprises a hoop to which are attached a plurality of flexible ribs, the tether being secured to the basket.

42. The assembly of claim 41 wherein the basket is constructed of resilient material and normally assumes a generally spherical configuration.

43. The assembly of claim 39 wherein the basket includes ribs that are joined at opposing ends and that are attached to a hoop.

44. The assembly of claim 39 wherein the basket ribs are formed of resilient material and normally assume a curved configuration.

45. The assembly of claim 39 wherein the basket hoop is formed of resilient material and normally assumes a curved configuration.

46. A method of converting a perforated ureteral stent into one that may be removed from a patient's ureter by use of a hook shaped instrument, the method comprising the step of attaching to one end of the stent an elongated tether to which tether is connected a basket, thereby enabling the basket to be disposed within the patient's bladder and accessible to a hook shaped instrument while the stent is in the ureter.

47. The method of claim 46 further including the step of sizing the stent so that the end of the stent to which the tether is attached is remote from the bladder while the stent is in the ureter and while the basket is disposed within the bladder.

48. A kit for converting a ureteral stent into one that may be removed from a

patient's ureter by use of a hook shaped instrument, wh rein the stent has a central lumen and at least one perforation, the kit comprising:

a collapsible basket; and

a tether connected to the basket, the tether including a loop that extends from the basket, thereby to enable the basket to be attached to a stent by the tether while the basket is remote from the stent; and

an elongated instrument sized to extend through both the lumen and perforation of the stent and engage the tether for connecting the tether to the stent.

49. A method of inserting a ureteral stent, comprising the steps of:

locating the stent within a patient's ureter; and

suspending from the stent a basket to be disposed in the bladder of the patient.

50. The method of step 49 wherein the suspending step includes the step of temporarily collapsing the basket while the basket is moved into the bladder.

51. The method of claim 49 wherein the locating step includes the step of guiding through a cystoscope as a unit that includes the basket, stent, a guide wire, and a pusher member.

Fig. 1

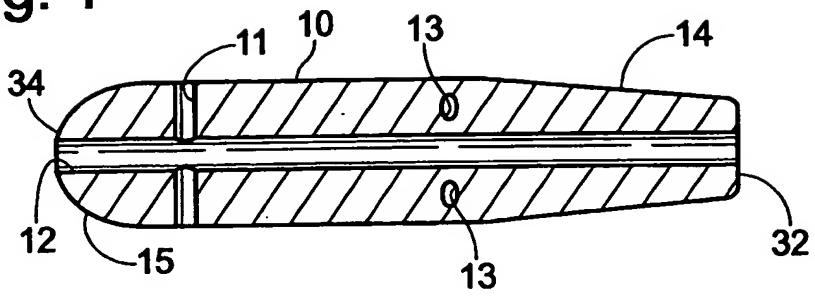


Fig. 2

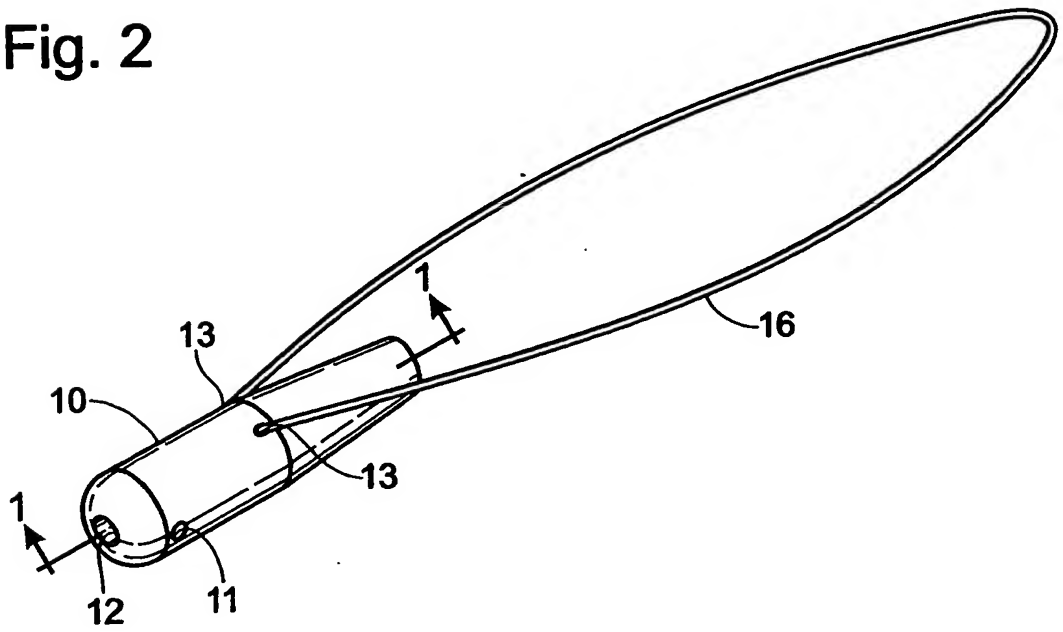


Fig. 3

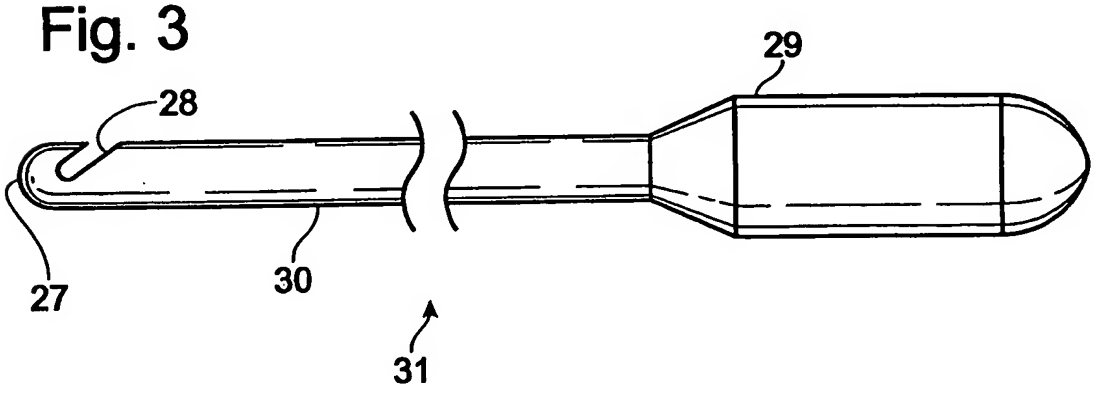
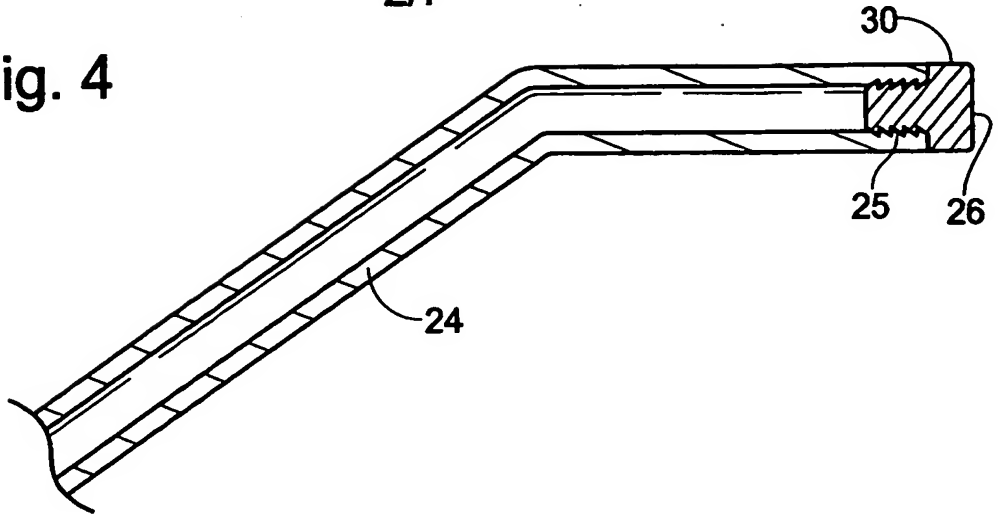
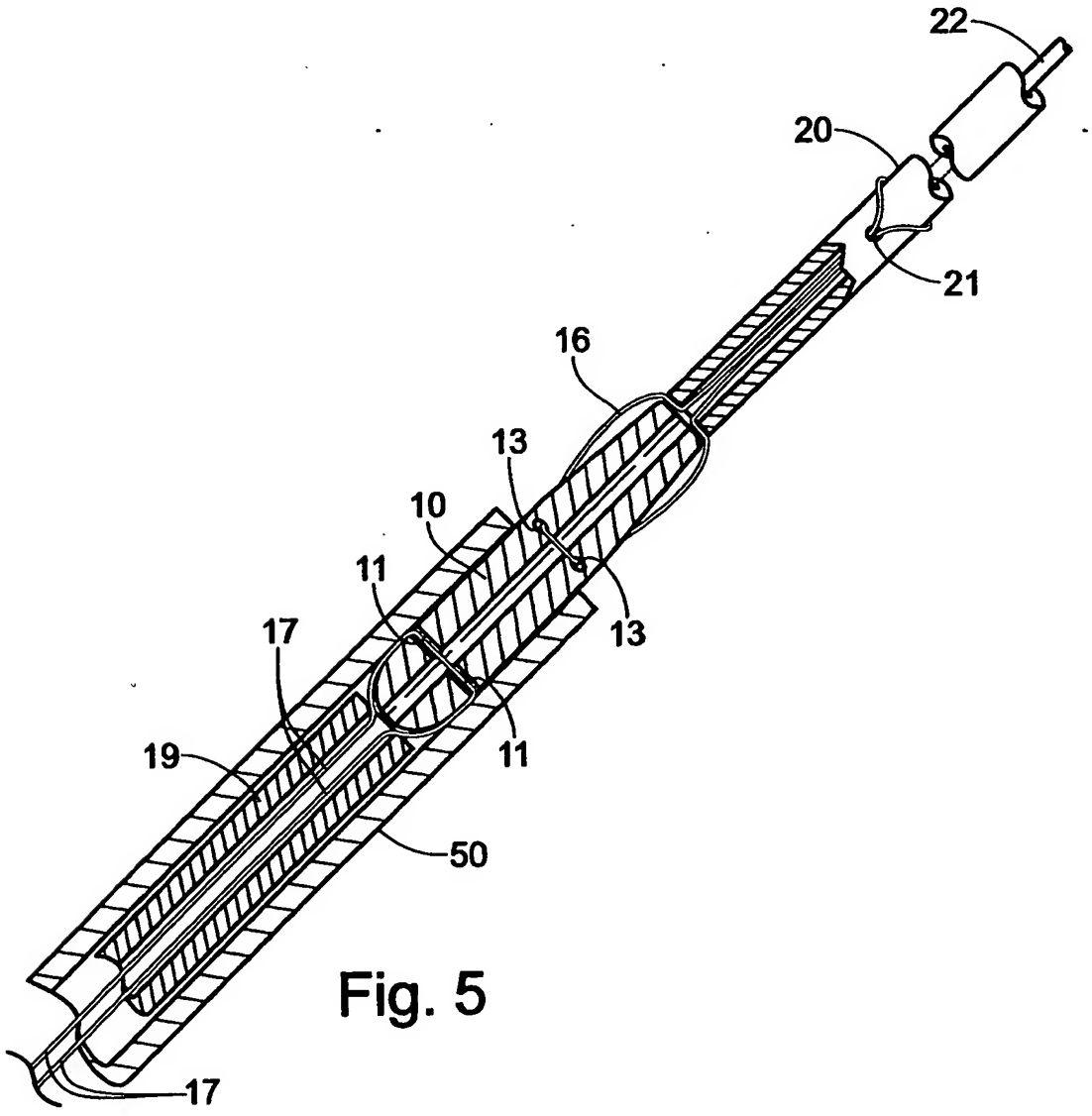


Fig. 4





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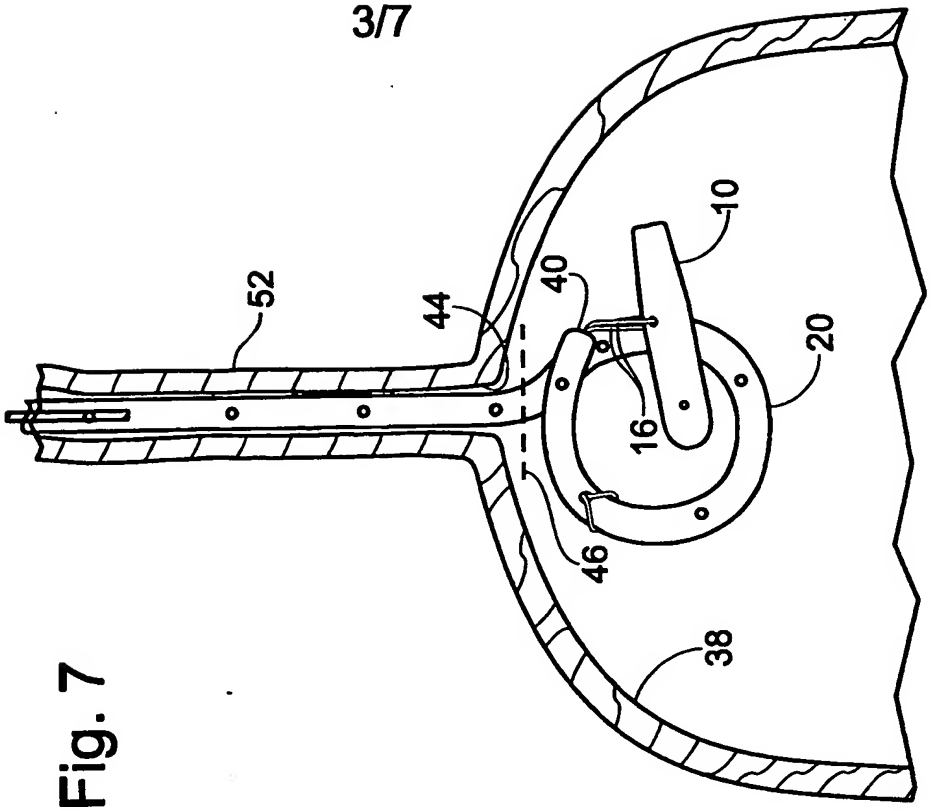

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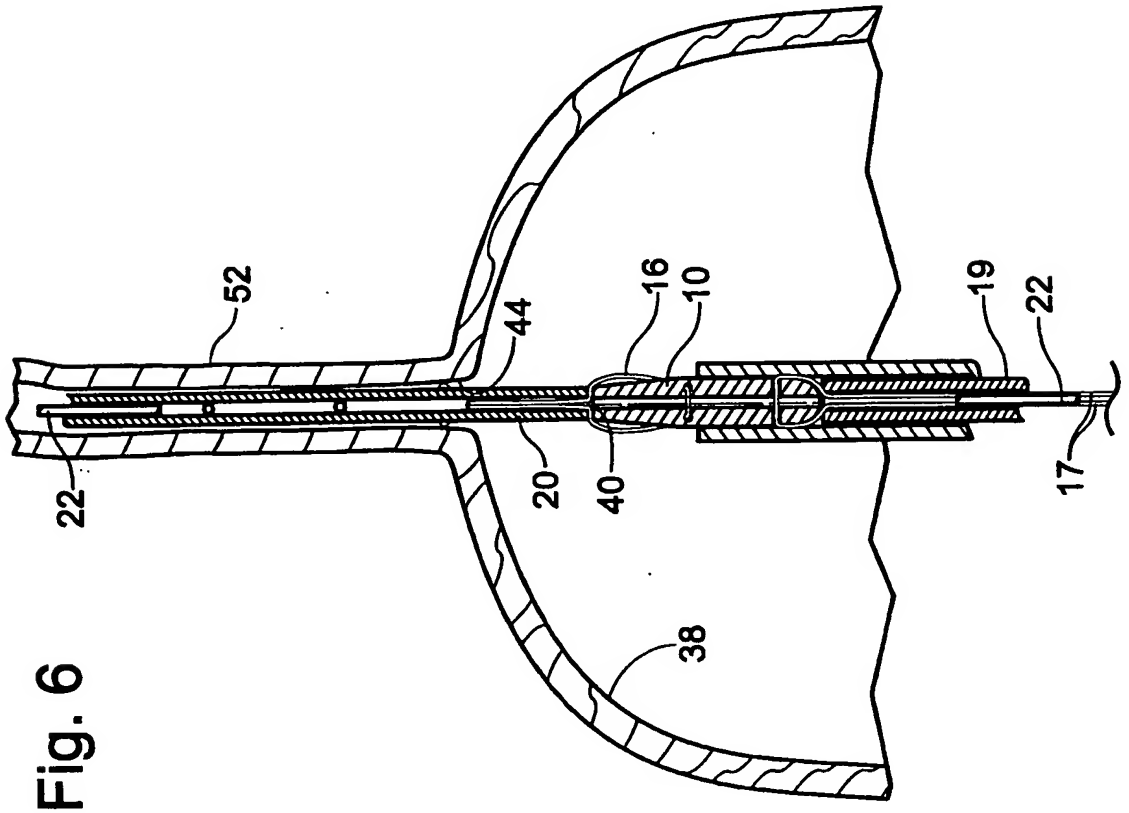

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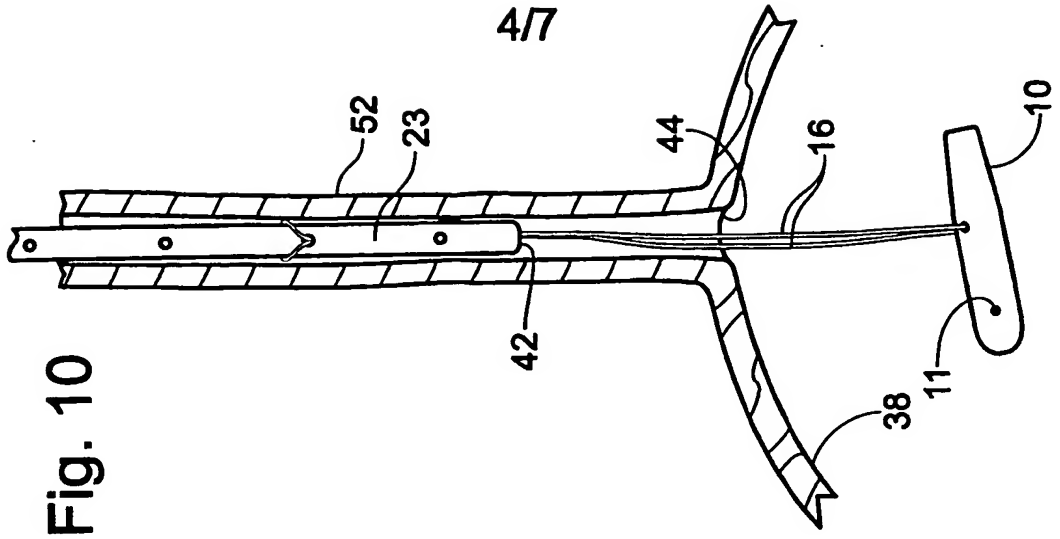


Fig. 10

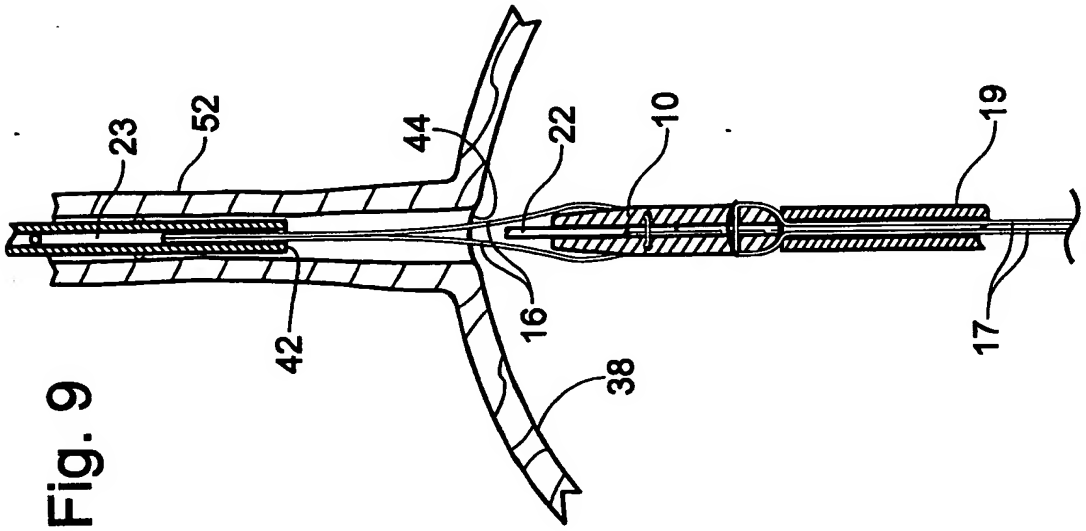


Fig. 9

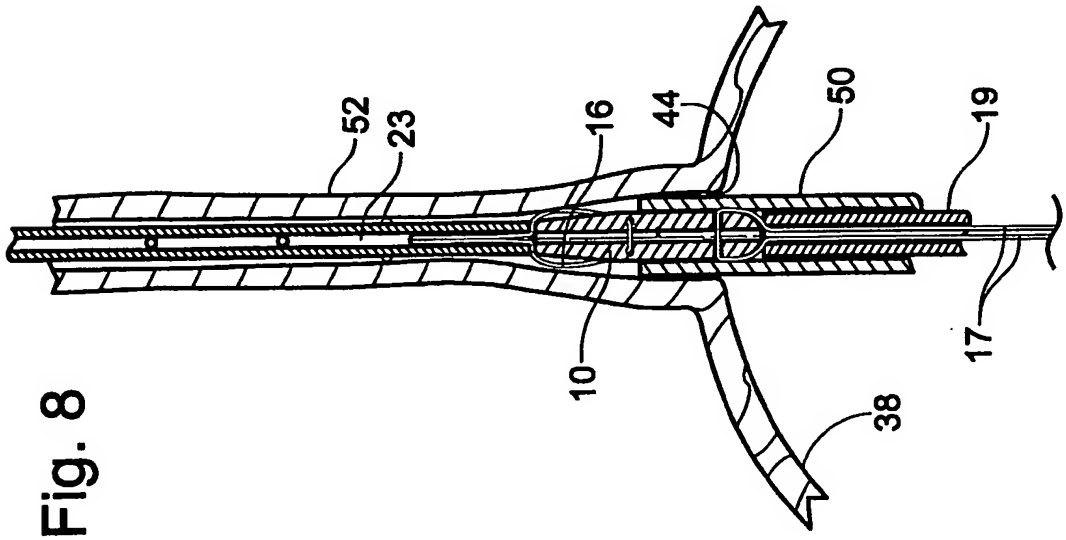


Fig. 8

Fig. 11

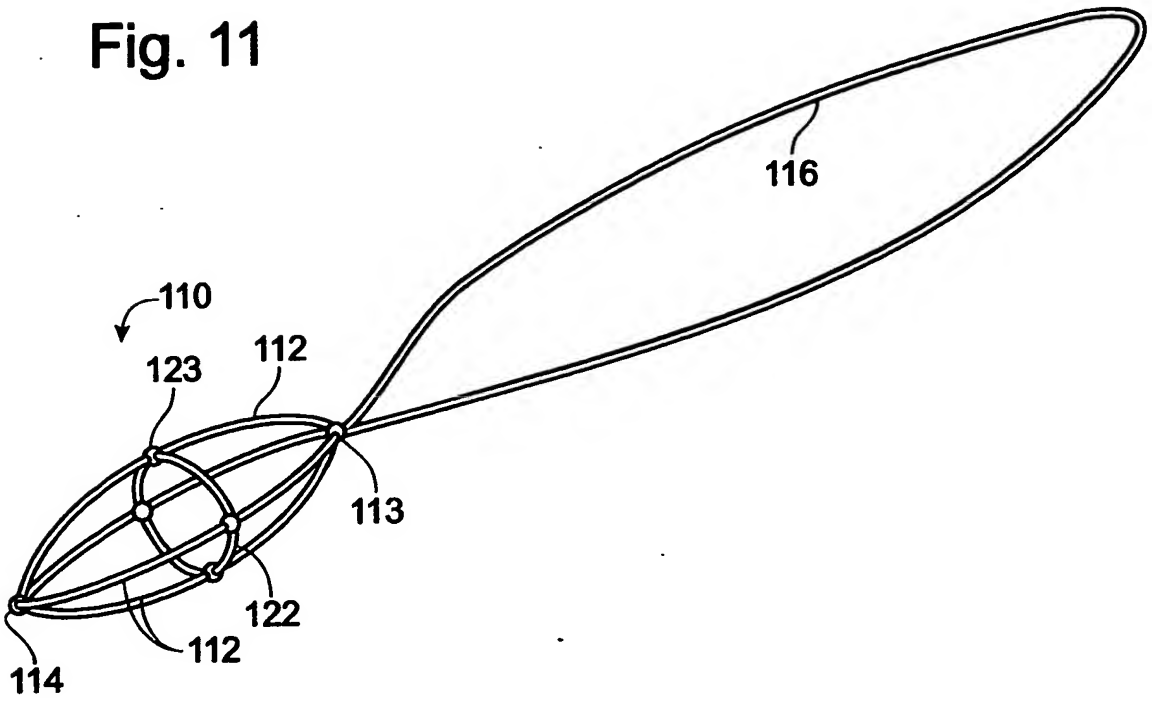


Fig. 12

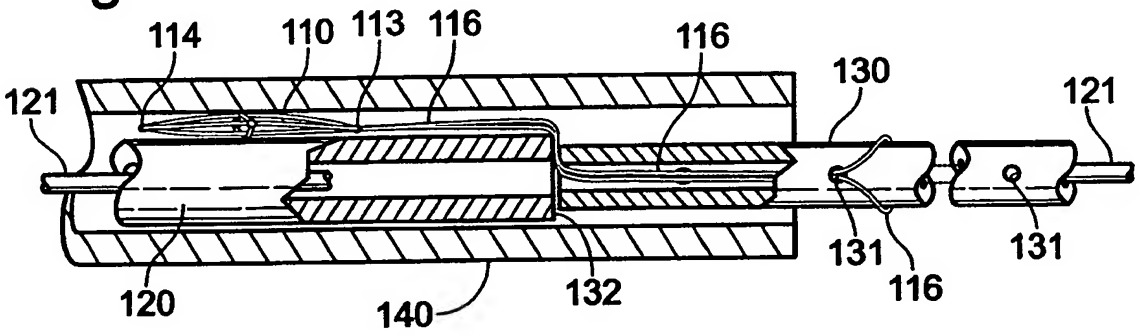
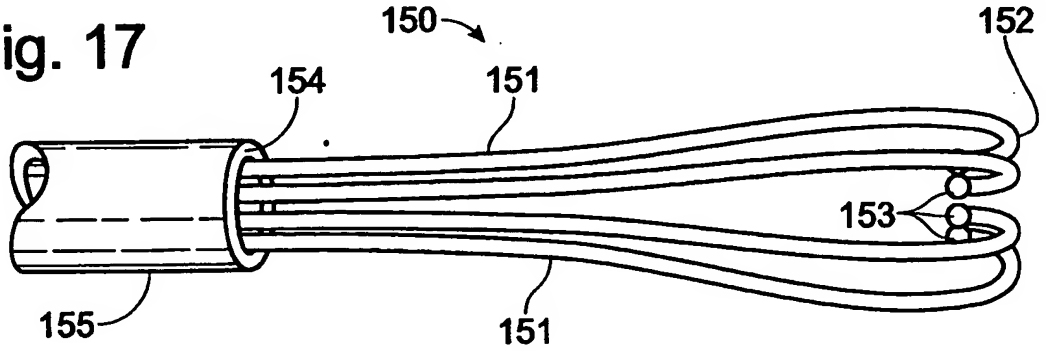


Fig. 17



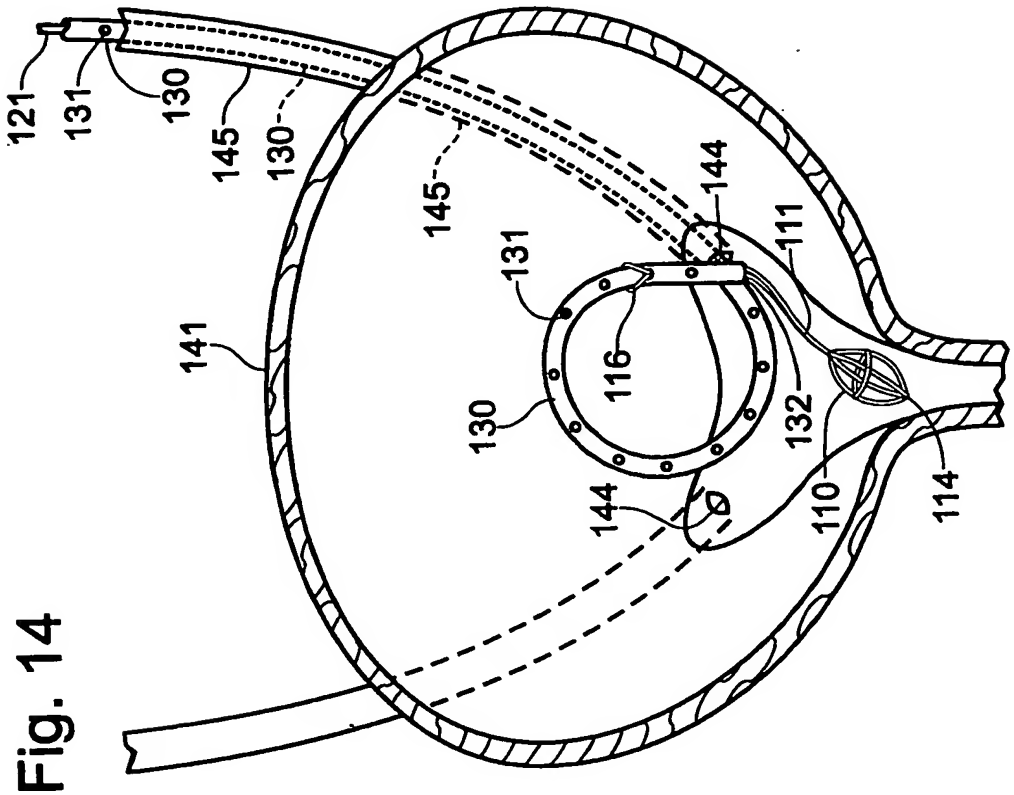

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Fig. 14

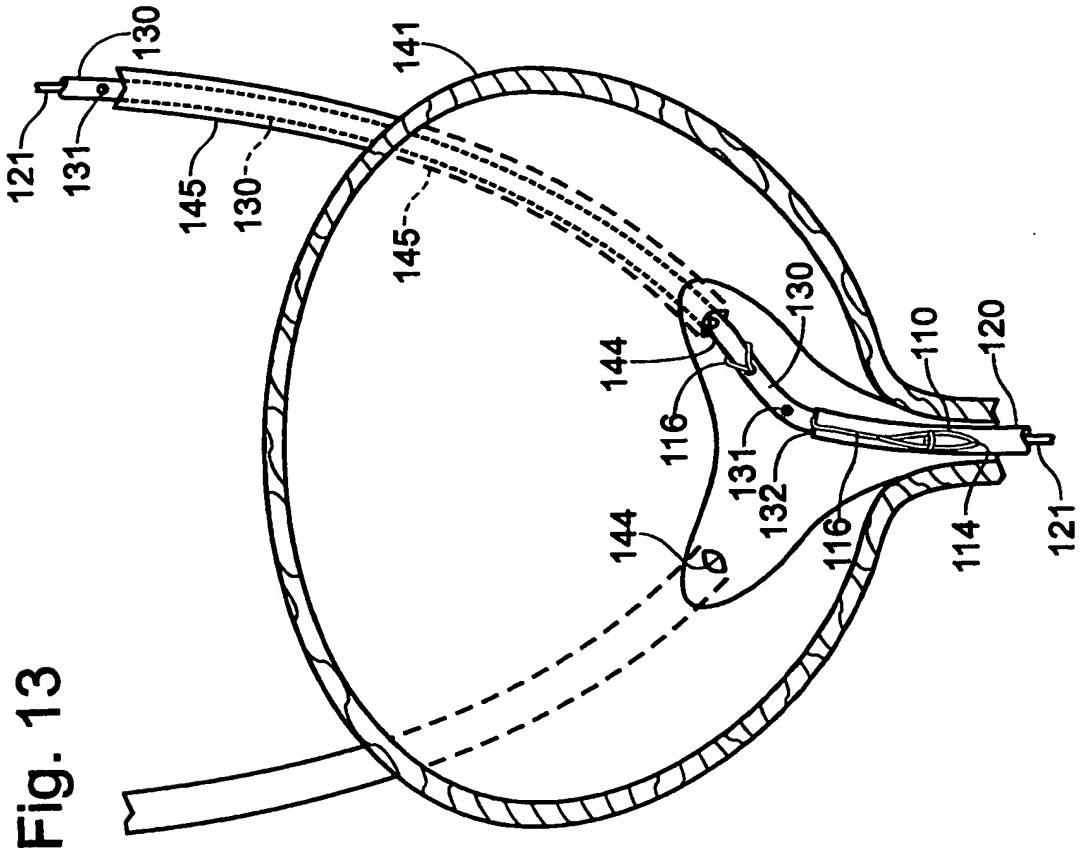
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Fig. 13

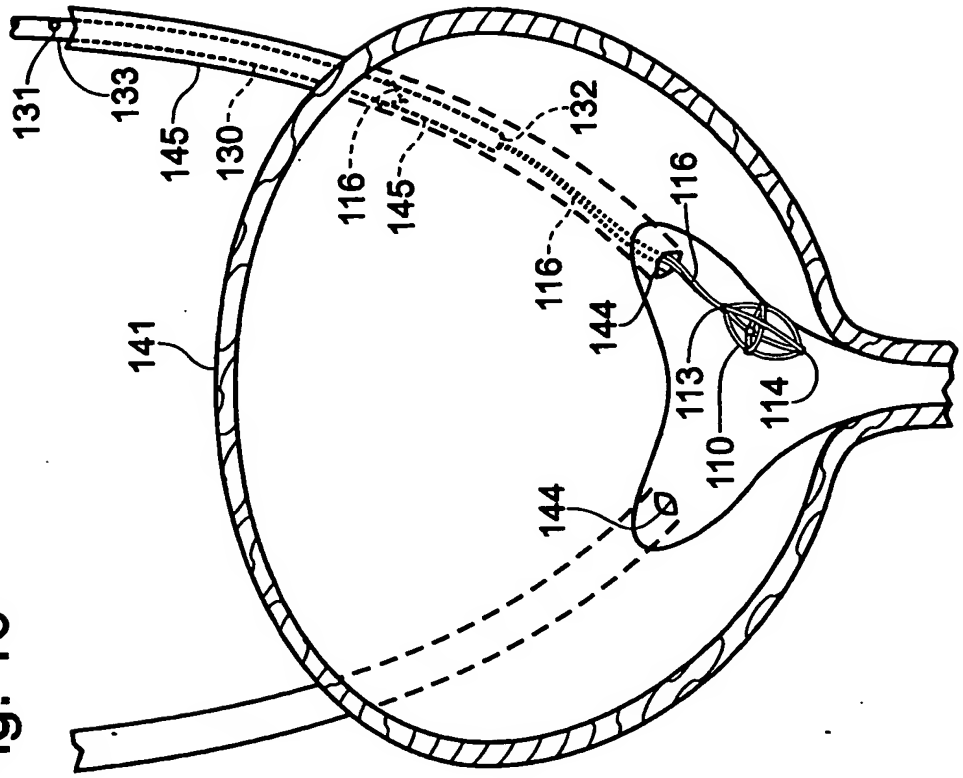
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Fig. 16

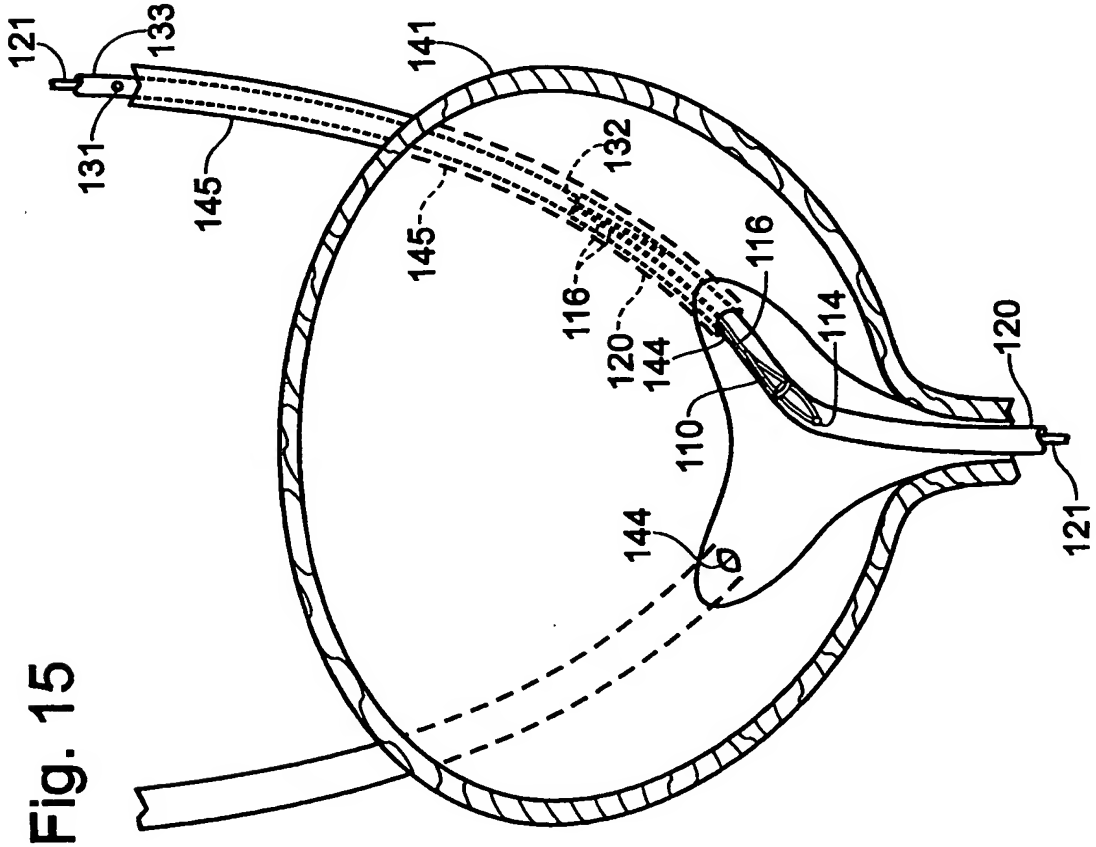
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Fig. 15

INTERNATIONAL SEARCH REPORT

In tional Application No
PCT/CA 99/00405

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/04 A61F2/06 A61F6/18

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	EP 0 276 104 A (AMERICAN MED SYST) 27 July 1988 (1988-07-27) column 7, line 15 - line 31; claims 18-20; figures 1,4	1 2,11-13, 21,23, 25,28, 39,46, 48,49
A	US 4 790 809 A (KUNTZ DAVID H) 13 December 1988 (1988-12-13) abstract; figures	1,12,21, 23,25
A	US 4 727 866 A (LIVESAY BILLY R ET AL) 1 March 1988 (1988-03-01) abstract; figures 5,6	1,11,12, 28

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 August 1999	23/08/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Kanal, P

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/CA 99/00405

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 3 908 646 A (ANSARI AMIR H) 30 September 1975 (1975-09-30) abstract; figure 3	1
A	US 5 116 309 A (COLL MILTON E) 26 May 1992 (1992-05-26) column 3, line 47 - line 49; figure 4	1
A	FR 2 577 809 A (SYNTHELABO) 29 August 1986 (1986-08-29) abstract; figure 1	1

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